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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/314,497	05/19/99	SCHINDLY	B MED-2-1012

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EXAMINER	
CHORBAJI, M	
ART UNIT	**PAPER NUMBER**
1744	9

DATE MAILED: 11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/314,497	Applicant(s) SCHINDLY ET AL.	
	Examiner MONZER R CHORBAJI	Art Unit 1744	

-- The MAILING DATE of this communication app ars on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *8* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This after final rejection is in response to the amendment received on 09/06/01

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minerovic et al (U.S.P.N. 5,997,814) in view of Ignacio et al (U.S.P.N. 6,287,518).

With respect to claims 1-7, and 22; Minerovic et al teaches of a package, col.2, line 12, which can be used in a single application, for holding a powdered composition, col.2, line 12, which forms a solution of an anti-microbial decontaminate when mixed with water, col.2, lines 13-14, and for selectively releasing the composition, col.3, lines 60-62, the package comprising: a porous portion, col.5, lines 63-67, and col.6, lines 33-35; first compartment for receiving a first component of the composition, second compartment for receiving a second component of the composition, col.2, lines 27-30, the porous portion, first compartment, and second compartment configured for forming a fluid flow path for the decontaminate solution through the package, col.6, lines 52-60, and col.10, lines 12-27; cartridge or package further includes: outer, first cup, figure 3 (50), including a first peripheral wall, figure 3 (52), with an opening at an end, figure 3 (60), the first peripheral wall being at least selectively water transmissive, col.8, lines 8-17, inner second cup, figure 3 (70), including a second peripheral wall, figure 3 (72), second peripheral wall being at least selectively water transmissive, col.8, lines 24-27, the first and second cups being configured such that the second peripheral wall abuts, figure 4 (74), and is connected to the first cup, figure 4 (54), adjacent the end of the first peripheral wall, figure 4 (52), top cover, figure 4 (94), covering the openings in the first and second cups, such that the first compartment, figure 4 (88), is defined in the first cup, figure 4 (50), and the second compartment, figure 4 (not labeled), is defined in the

second cup, figure 3 (70); first peripheral wall includes a region which is formed from a first material, col.9, lines 54-56; first cup peripheral wall includes a side and a base, figure 3 (50, 52, and 60), and wherein the base is detachable from the side, figure 4 (58); second peripheral wall, figure 4 (72), includes a region which is formed from a second material, col.9, lines 56-57, which is impermeable to the first and second components but is permeable to water and to solutions containing dissolved components, col.8, lines 57-62, second peripheral wall defines a hemisphere and is formed from the second material, figure 4 (72).

With respect to claims 8-10, and 15-17; Minerovic et al teaches the following: a top cover defines the porous portion, col.9, lines 34-35; porous portion is formed from non-woven polypropylene web, col.6, lines 24-27; decontaminate includes peracetic acid, col.7, line 10, first component includes acetylsalicylic acid and the second component includes sodium perborate, col.10, lines 1-3.

With respect to claims 19-21; Minerovic et al teaches the following: a well, figure 2 (16), for receiving the package of claim 1, source of water connected with the well, col.5, lines 9-16, for mixing with the powdered composition to form the antimicrobial solution, a microbial decontamination chamber, figure 2 (C), connected with the well for receiving the anti-microbial solution, the well the porous region and the chamber forming a re-circulating fluid flow path for the decontaminate solution, col.4, lines 66-67, and col.5, lines 1-31; package for releasing an antimicrobial composition into a flowing liquid, comprising: side wall, figure 3 (52), having a first opening, figure 3 (56), at a first

end, and a second opening, figure 3 (60), at a second end such that the liquid flows through the first opening into the package and out through the second opening, layer of porous material, figure 4 (94), spanning one of the first and second openings such that the liquid flows through the porous material layer, figure 2 (C, 16, 28, 24, 14, and 12), an antimicrobial source is disposed within the package, figure 4 (88), for releasing the antimicrobial composition into the flowing liquid, figure 2 (C, 16, 28, 24, 14, and 12), to form an antimicrobial solution. Minerovic et al further teaches of a method including all the limitations mentioned above, columns 10-12. In addition, Minerovic et al teaches of using measured amounts of the reagents to form the required concentration of the sterilant to effect sterilization (col.2, lines 1-3) and also uses the word "metering" a preselected amounts of both reagents (col.3, lines 24-45).

With respect to claims 1, 8, and 11-21; Minerovic et al fails to teach the use of an indicator.

With respect to claims 1, 8, and 19, Ignacio et al teaches the use of an indicator, which exhibits a detectable change on exposure to the decontaminant in the solution (col.1, lines 47-52). Furthermore, Ignacio et al teaches that the location of the indicator can be placed any where on the single-use package (col.9, lines 54-62) including on a porous portion of the top cover or the like.

With respect to claims 11-15 and 20-21, Ignacio et al teaches the following: various time contacts (see examples 1-6); indicator is specific for the decontaminant (abstract, lines 4-5); indicator is less sensitive to PH than to the decontaminant (col.7,

lines 1-3 and also Ignacio et al shows various concentration ranges which inherently constitutes various PH values where the indicator is functioning); indictor is impregnated into the porous portion in the form of an ink (figure 1, 40 and col.4, lines 14-18); and where the indicator exhibits a detectable color based on proper concentration and time (col.1, lines 62-67).

With respect to claims 16-18, Ignacio et al teaches the following: the decontaminant is peracetic acid (col.1, lines 45-47) and the indicator provides a detectable color change when the peracetic acid is at a concentration of about 900ppm for a preselected period of time (col.8, table showing the various concentrations of peracetic acid); the indicator is bromocresol green (col.6, line 38); and the indicator is crystal violet (col.6, line 31). Thus, one skilled in the art would have been motivated to combine Minerovic et al with Ignacio et al in order to insure that sterilization processes are effective and meet certain pre-determined sterilization parameters (Ignacio et al, col.1, lines 17-20 and lines 62-67).

Response to Arguments

5. Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. Thukamoto et al (U.S.P.N. 4,206,844) and Antonoplos et al (U.S.P.N. 5,942,438) teach of using indicators in the art of sterilization.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-7719 for After Final communications.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
October 11, 2001

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